MANAGEMENT CHALLENGES FOR FY 2014

On July 9, 2012, the President signed the Food and Drug Administration Safety and Innovation Act (FDASIA) into law. Title I of FDASIA includes the fifth authorization of PDUFA (PDUFA V). The new law ensures that FDA will continue to receive this additional source of stable and consistent funding during FY 2013-2017, enabling FDA to protect and promote public health by helping to bring critical new medicines to market.

PDUFA V addressed many of the top priorities identified by public stakeholders, the top concerns identified by industry, and the most important challenges identified within FDA. PDUFA V enhancements included increased interaction during regulatory review of New Molecular Entity New Drug Applications (NME NDAs) and original Biologics License Applications (BLAs); regulatory science enhancements to expedite drug development; the development of important new guidance for industry on such topics as Risk Evaluation and Mitigation Strategies and best practices for conducting meta-analyses; a commitment to develop a structured framework for benefit-risk assessment; various enhancements to the drug safety system; and requirements for electronic submissions and standardization of electronic application data. This additional work was funded by a 6 percent increase in PDUFA user fees.

Under the Budget Control Act of 2011, $34.2 million of the PDUFA user fees collected in FY 2013 were sequestered and not available for obligation (see Footnote 1 on page 10). FDA's work over the past year in implementing PDUFA V and the additional requirements in FDASIA such as the new breakthrough therapy program has all been accomplished by our 2012 PDUFA staffing level, not the staffing level deemed necessary for this work. Nonetheless, the committed public health professionals at FDA have made significant and steady progress in meeting these commitments and statutory requirements. For example, the new review program for NMEs and Original BLAs and our enhanced communication with sponsors during drug development were both open for business on October 1, 2012. FDA also published a draft implementation plan for a structured approach to benefit-risk assessment, a guidance on our expedited drug review programs, and we conducted four public meetings during FY 2013 under our Patient-Focused Drug Development initiative.

While FDA's accomplishments in FY 2013 are important and promise to have long-term positive impacts on public heath, we look forward to the future when FDA has access to the total amount of user fee funding that is intended to support the agency's work.